IBRAMED

SECTION 6

510(k) Summary

Neurodyn Multiwave

NOV 2 6 2013

510 (k) Number: K131629

Date of Submission: November 25, 2013

Submitter:

IBRAMED EQUIPAMENTOS MEDICOS
Avenida Dr. Carlos Burgos 2800
Amparo – Sao Paulo – Brasil

TEL – 5519-3817-9633
FAX – 5519-7816-7980

Official Contact:

Lilian Llull
TechLink International Consulting
18851 NE 29th Avenue
Suite 720
Aventura, FL 33180

TEL – (305) 377-0077

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510 (k) premarket notification is in accordance with 21 CFR 807.87.

Common (Standard) Name: Powered Muscle Stimulator
Trade Name: Neurodyn Multiwave; Aussie Sport

Regulation Number & Product Codes:
GZJ - 21 CFR 882.5890-Transcutaneous electrical nerve stimulator for pain relief
IPF - 21 CFR 890.5850-Powered muscle stimulator
LIH - Interferential Current Therapy-Pre-amendment
GZI- 21 CFR 882.5890-External functional neuromuscular stimulator

Predicate Device Identification:
K121369 Neurodyn/Neurodyn Aussie Powered Muscle Stimulator
K021100 300 PV Complete Electrotherapy
K031077 Vectra Genisys

Predicate devices had been submitted and cleared by 510(k) for the same intended uses and

IBRAMED

indications.

Device Description

Neurodyn Multiwave and Aussie Sport Neuromuscular Stimulators are intended for the treatment of, relief of chronic (long term) intractable pain as adjunctive treatment of post-surgical and post-traumatic acute pain. Both devices have the same intended uses and incorporate the same technologies as the following predicate devices: Vectra Genisys K031077, Neurodyn/Neurpdun Aussie K121369 and 400PV Complete K021100.

The Neurodyn Multiwave Muscle Stimulator is a programmable device. It comes equipped with 5 preset clinical programs along with 10 user protocols. The user programs are adjustable and can be changed according to the patient's needs, doctor's recommendations and prescription settings.

The Aussie Sport Muscle Stimulator has four output channels with independent intensity controls. Thus, four different areas can be stimulated separately or together during a therapy session. It is adjustable and can be changed according to the patient's needs, doctor's recommendations and prescription settings. It generates the medium frequency alternate current(MFAC), burst modulated alternating current (Aussie)- type of sinusoidal current with a frequency carrying 1,000 Hz or 4,000 Hz and a burst duration of 4 ms or 2 ms, modulated in pulse trains (bursts) with a variable frequency from 1 to 120Hz.

Indications for Use

Neurodyn Multiwave-Indications for Use:

As a FES device:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

As a TENS device:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post surgical pain

As an Interferential and Premodulated device:
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Russian device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions

IBRAMED

- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Microcurrent device:
- Symptomatic relief of chronic intractable pain
- Symptomatic relief of post-traumatic acute pain and post surgical pain

As a DC/Polarized device:
-Relaxation of Muscle Spasm

Aussie Sport- Indications for Use:

As an Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

Essential Performance

Neurodyn Multiwave Muscle Stimulator produces the following currents:
Russian/Aussie /Interferential /Tens /Premodulated / Microcurrent/FES/DC Polarized.

The Aussie Sport Muscle Stimulator produces an Aussie current.

Summary of Safety and Effectiveness Conclusion

The Neurodyn Muscle Stimulators are substantially to the predicate devices. All five devices claim similar Indications for Use and Device Characteristics in technological design and materials. The Neurodyn Muscle Stimulators do not raise any new issues of Safety and Effectiveness based on their similarities. The devices have continually proven to be safe and effective and demonstrate intended product performance.

Device Comparison Table

Device name	Neurodyn Multiwave	Neurodyn	300 PV Empi	Vectra Genysis	Aussie Sport	Aussie
K Number	K131629	K121369	K021100	K031077	K131629	K121369
Manufacturer	Ibramed	Ibramed	Empi	Chattanooga	Ibramed	Ibramed
Indications for Use	As a FES device: Stimulation of the muscles in the leg and ankle of partially paralyzed patients to		As a FES device: Stimulation of muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot	As a FES device: Stimulation of muscles in the leg and ankle of partially paralyzed patients to provide flexion of		

IBRAMED

	provide flexion of the foot and thus improve the patient's gait.		and thus improve the patient's gait. As a NMES device: Retarding or preventing disuse atrophy Maintaining or increasing range of motion Reeducating muscles Relaxation of muscle spasm Increasing local blood circulation Prevention of venous thrombosis of the calf muscles immediately after surgery	the foot and thus improve the patient's gait.		
	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain		
	As an Interferential and Premodulated device: Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain	As an Interferential and Premodulated device: Symptomatic relief of chronic pain, acute post traumatic pain, or acute post traumatic surgical pain	As an Interferential This device is not been used as a predicate for the Interferential waveform	As an Interferential and Premodulated device: Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain		
	As a DC/Polarized device: Relaxation of Muscle Spasm			As a DC/ Mode device: Relaxation of Muscle Spasm		
	As a Burst Modulated Alternating Current -Russian device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education	As a Burst Modulated Alternating Current -Russian device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education		As a Burst Modulated Alternating Current -Russian device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education		

IBRAMED

	Maintaining or increasing range of motion	Maintaining or increasing range of motion		Maintaining or increasing range of motion		
	As an Burst Modulated Alternating Current (Aussie) device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education Maintaining or increasing range of motion Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain	As a Burst Modulated Alternating Current (Aussie) device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education			As a Burst Modulated Alternating Current (Aussie) device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education	As an Burst Modulated Alternating Current (Aussie) device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education Maintaining or increasing range of motion Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain
	As a Microcurrent device: Symptomatic relief of chronic intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a Microcurrent device: Symptomatic relief of chronic intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain		As a Microcurrent device: Symptomatic relief of chronic intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain		
Technological characteristics Medium-frequency alternating current (MFAC)	Identical	Identical	Identical	Identical	Identical	Identical
Device Material	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display
Width (in)	6.8	6.8	9.75	1.26	6.8	6.8
Height	4.9	4.9	8.75	3.3	4.9	4.9
Depth	12.4	12.4	12.75	4.5	12.4	12.4
Number of Channels	4	4	4	4	4	4
Temperature range during transport and storage	45°f-110°f	45°f-110°f	-40 to 158°F	-40 to 150 F	45°f-110°f	45°f-110°f
Environment operating	45°F-110°F	45°F-110°F	50° to 104°F	45 to 105° F	45°F-110°F	45°F-110°F

temperature range						
Performance	Identical	Identical	Identical	Identical	Identical	Identical
Biocompatibility	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrodes
Mechanical Safety	Identical	Identical	Identical	Identical	Identical	Identical
Anatomical Sites	Identical	Identical	Identical	Identical	Identical	Identical
Russian	Yes	Yes	No	Yes	No	No
Aussie	Yes	Yes	No	Yes	Yes	Yes
Interferential	Yes	Yes	Yes	Yes	No	No
Microcurrent	Yes	Yes	No	Yes	No	No
TENS	Yes	Yes	Yes	Yes	No	No
Premodulated	Yes	Yes	Yes	Yes	No	No
FES	Yes	No	Yes	Yes	No	No
DC/Polarized	Yes	No	No	Yes	No	No
Voltage Input	100/240V 50/60Hz Bivolt	100/240V 50/60Hz Bivolt	3.0V DC	100/240V 50/60Hz 1.0A	100/240V 50/60Hz Bivolt	100/240V 50/60Hz Bivolt
Output	5A+17V	5A+17V	1.0A+3.0V DC	7.3A+24V	5A+17V	5A+17V
Method of line current isolation	Double Isolation	Double Isolation	Double Isolation	Double Isolation	Double Isolation	Double Isolation
Patient leakage control-normal condition	0.0508mA	0.0508mA	0.0502mA	69μA	0.0508mA	0.0508mA
Patient leakage current-single fault condition	0.0252mA	0.0252mA	0.0248mA	31μA	0.0252mA	0.0252mA
Software microprocessor	Yes	Yes	Yes	Yes	Yes	Yes
Automatic overload trip	No	No	No	No	No	No
Automatic shutoff	No.	No	No	No	No	No
Locking feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature
Treatment timer	1 to 60 minutes	1 to 60 minutes	5 to 60 minutes	1 to 60 minutes	1 to 60 minutes	1 to 60 minutes
Auto test and repeat	Treatment timer with auto shut off	Treatment timer with auto shut off	Treatment timer	Treatment timer with auto shut off	Treatment timer with auto shut off	Treatment timer with auto shut off
Frequency Range	.50/60Hz	50/60Hz	---	50/60Hz	50/60Hz	50/60Hz
Maximum Current Density	2.0 mA	2.0 mA	2.0 mA	2.0 mA	2.0 mA	2.0 mA

Conclusion

This premarket notification is being submitted to request clearance for the Neurodyn Muscle Stimulators. The analysis on the device demonstrates substantial equivalence to the Ibramed Neurodyn, Vectra Genisys, and EMPI 300 PV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Ibramed Equipamentos Medicos
c/o Ms. Lilian Llull
Techlink International Consulting
18851 NE 29th Avenue Suite 720
Aventura, FL 33180

Re: K131629
Trade/Device Name: Neurodyn Multiwave and Aussie Sport
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, LIH, GZI
Dated: October 25, 2013
Received: October 28, 2013

Dear Ms. Llull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131629

Device Name: Neurodyn Multiwave and Aussie Sport

Indications For Use:

Neurodyn Multiwave - Indications for Use:
As a FES device:

- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

As a TENS device:

- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical pain

As an Interferential and Premodulated device:

- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Russian device:

- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:

- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Microcurrent device:

- Symptomatic relief of chronic intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical pain

As a DC/Polarized device:

- Relaxation of Muscle Spasm

Aussie Sport - Indications for Use:

As an Burst Modulated Alternating Current (Aussie) device:

- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S